

## CLOSEOUT LETTER

**23andMe, Inc.****MAR 25, 2014****Exhibit B**

23andMe, Inc.



Department of Health and Human Services

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

March 25, 2014

Mrs. Anne Wojcicki  
Co-Founder & Chief Executive Officer  
23andMe, Inc.  
1390 SHOREBIRD WAY  
MOUNTAIN VIEW, CA 94043

Dear Mrs. Wojcicki:

The Food and Drug Administration has completed an evaluation of your firm's corrective actions in response to our Warning Letter CMS 415534 dated November 22, 2013. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter.

Your firm's response to our Warning Letter appears to be adequate. This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

/S/

Alberto Gutierrez  
Office of In vitro Diagnostics and  
Radiological Health  
Center for Devices and Radiological Health[More Warning Letters \(/web/20190721180527/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters\)](https://web.archive.org/web/20190721180527/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)